



# PATIENT INSTRUCTIONS FOR USE



Instructions for  
SPRINT® PNS Systems

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The SPRINT® PNS System is manufactured by:



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[SprintPNS.com](http://SprintPNS.com)

**Information on patents can be found at:**  
[sprtherapeutics.com/patents](http://sprtherapeutics.com/patents)

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# TABLE OF CONTENTS

<b>Glossary</b> .....	<b>4</b>
<b>1 Introduction</b> .....	<b>5</b>
1.1) About this Manual.....	5
1.2) Peripheral Nerve Stimulation (PNS) Treatment .....	5
1.3) Your SPRINT® PNS System.....	6
<b>2 Important Safeguards</b> .....	<b>8</b>
2.1) Purpose of the Device (Indications for Use) .....	8
2.2) When the Device Should not be Used (Contraindications).....	8
2.3) Warnings, Precautions, & Risks.....	9
<b>Quick Reference Sections</b>	
<b>3 Using Your SPRINT® PNS System</b> .....	<b>16</b>
3.1) Start and Stop Stimulation.....	16
3.2) Using Your Pulse Generator.....	17
3.3) Operating Your Hand-Held Remote.....	18
3.4) Home Screens: ON and OFF for Each System.....	19
3.5) Adjusting Stimulation .....	22
<b>4 Connecting &amp; Disconnecting the System</b> .....	<b>25</b>
4.1) Connecting the System.....	25
4.2) Disconnecting the System.....	29
<b>5 Cleaning &amp; Care</b> .....	<b>31</b>
5.1) Caring for the MicroLead Exit Site(s).....	31
5.2) Changing the Waterproof Bandage(s) and Mounting Cradle(s) .....	32
5.3) System Cleaning .....	35
5.4) Disposal.....	35
<b>6 Battery &amp; Charging Your System</b> .....	<b>36</b>
6.1) Checking the Rechargeable Battery Level .....	37
6.2) Charging the Battery .....	38
6.3) Removing / Changing the Battery .....	39
<b>7 Timed/Session Treatment vs Continuous Treatment</b> .....	<b>40</b>
7.1) Your Treatment Type .....	40
7.2) Session Countdown Timer.....	41
7.3) Bimodal™ Systems Only.....	42
<b>APPENDIX A Frequently Asked Questions</b> .....	<b>43</b>
<b>APPENDIX B Troubleshooting</b> .....	<b>44</b>
<b>APPENDIX C Specifications</b> .....	<b>50</b>
<b>APPENDIX D Symbols and Messages</b> .....	<b>54</b>
<b>APPENDIX E Contacting Customer Service</b> .....	<b>58</b>
<b>APPENDIX F MRI Safety Information</b> .....	<b>59</b>
<b>APPENDIX G TSA information</b> .....	<b>62</b>

## GLOSSARY

**Bimodal** – Stimulation configuration applicable to a Dual-Lead device when each Lead is providing different treatment modalities. This configuration is determined by your provider.

**Caution** – Information on how to prevent damage to or failure of your device.

**Configuration** – How your provider set up your System. Configurations include Single-Lead, Dual-Lead, Bimodal, and stimulation settings.

**Contraindication** – When you should not use the SPRINT® PNS System.

**Diathermy** – A medical treatment applied to the outside of the body that delivers heat into the body.

**Indication** – The purpose of the SPRINT® PNS System.

**Intensity** – The strength of your stimulation.

**Magnetic Resonance Imaging (MRI)** – A medical test that lets doctors see inside your body.

**Note** (📌) – An important reminder for the use of your System.

**Precaution** – See Caution.

**Provider** – Your doctor that provides you with the SPRINT® PNS System.

**Stimulation** – The delivery of tiny electrical pulses to a nerve to cause therapeutic sensations.

**Treatment** – Treatment of a disease or condition. This System uses stimulation as its treatment.

**Warning** (⚠️) – Describes an action or situation that could harm you or others.

# 1 INTRODUCTION

## 1.1) About this Manual

This manual describes your SPRINT® PNS System. It provides important use and safety information. Before you begin using your System, read this manual completely. Contact your provider if you have any questions or concerns. Keep your manual in a safe place, so you can refer to it in the future.

This manual is applicable to the SPRINT Family of products. Images and screens will vary based on how your System is configured by your provider.

## 1.2) Peripheral Nerve Stimulation (PNS) Treatment

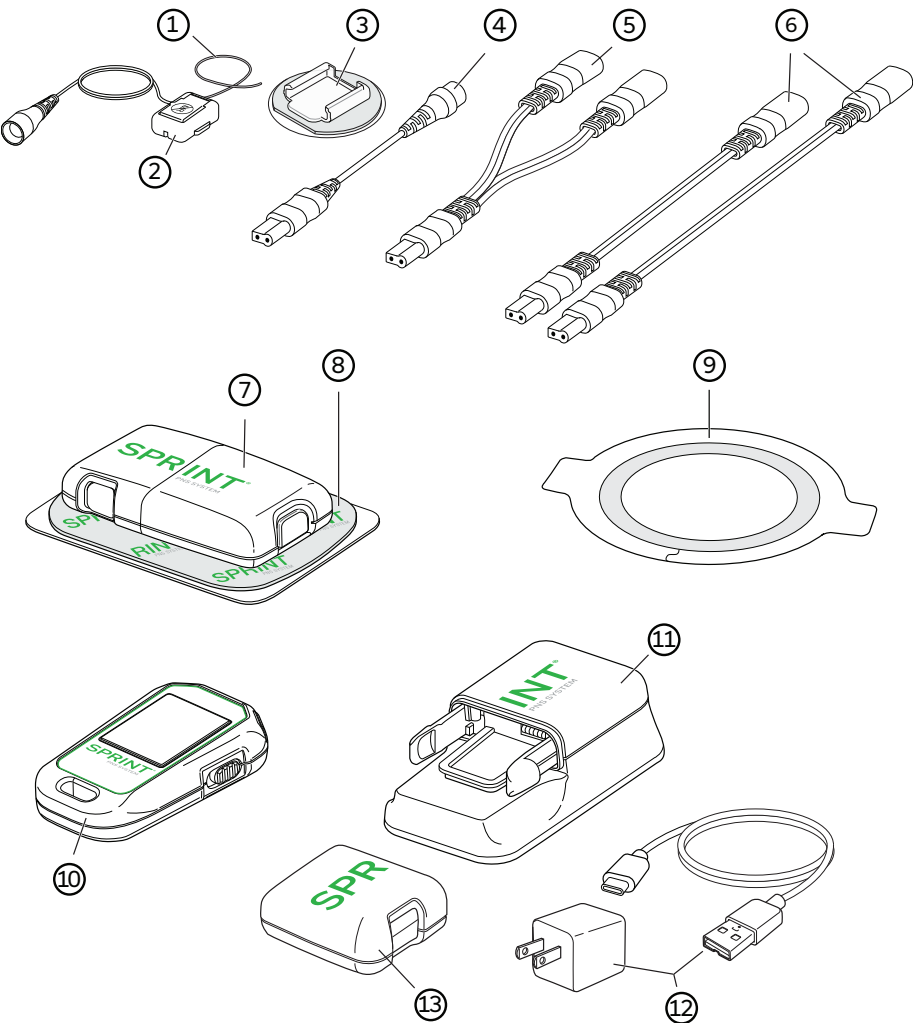
Your SPRINT System uses a small, wearable Pulse Generator (power source) connected to a MicroLead. The Lead is a thread-like wire that delivers tiny electrical pulses, called stimulation. This stimulation targets specific nerves tied to the pain site. This is intended to relieve your pain. The Lead will be removed by your provider at the end of the treatment.

The System includes a Remote. The Remote lets you control your Pulse Generator and adjust the stimulation intensity.



**NOTE:** It is important that you follow the instructions given by your provider. They will show you how to set up your System and care for your skin, including the Lead exit site. Follow your provider's guidelines for best results.

1.3) Your SPRINT® PNS System



1. **MicroLead (REF 80067):** A thin, thread-like wire. One end is inserted through your skin near a nerve. The other end remains outside of your body and attaches to the Pulse Generator using the MicroLead Connector and Cables. A MicroLead is sometimes referred to as just "Lead".
2. **MicroLead Connector:** Connects the MicroLead to the Magnetic Coupler.
3. **Mounting Cradle:** Holds the MicroLead Connector in place under the Bandage.
4. **Magnetic Coupler:** Connects the MicroLead Connector to the Pulse Generator. If your System is pulled or bumped, the magnets will separate to help keep the MicroLead in place.
5. **Dual Lead Adapter (Dual-Lead Systems only):** The adapter connects two MicroLead Connectors to one Pulse Generator.
6. **Short & Long Extensions:** Cables that provide extra length.
7. **Pulse Generator (REF 9610):** Delivers your peripheral nerve stimulation (PNS) treatment.
8. **Mounting Pad:** Connects the Pulse Generator to your skin. One side of the Mounting Pad has a sticky gel to attach the pad to your skin. The non-sticky side of the Mounting Pad has two snaps that connect to the Pulse Generator.
9. **Waterproof Bandage:** Keeps your MicroLead exit site clean and dry. (Your Bandage may look different than the illustrations in this manual.)
10. **Hand-Held Remote (REF 9620):** Allows you to turn stimulation on and off and adjust intensity.
11. **Recharging Base (REF 9615):** Charges your Pulse Generator Rechargeable Batteries.
12. **Recharging Base Power Supply (REF 9616):** Power cord for your Recharging Base.
13. **Rechargeable Battery (REF 9612):** The Pulse Generator needs one Rechargeable Battery. Two batteries are provided so you can charge one while the other is in use.
14. **Patient Case (not pictured):** Includes Recharging Base, extra Battery, Mounting Cradles, Mounting Pads.



**NOTE:** Contact your provider if anything is missing or broken.

## 2 IMPORTANT SAFEGUARDS

Carefully read the following information before using your SPRINT System. If you have any questions, call your provider.

### 2.1) Purpose of the Device (Indications for Use)

The SPRINT® Peripheral Nerve Stimulation (PNS) System is indicated for up to 60 days for:

- Symptomatic relief of chronic, intractable pain, post-surgical and post-traumatic acute pain;
- Symptomatic relief of post-traumatic pain;
- Symptomatic relief of post-operative pain.

The SPRINT® PNS System is not intended to treat pain in the region innervated by the cranial and facial nerves.

A randomized controlled trial failed to show that the SPRINT System was effective for poststroke shoulder pain.

Safety and effectiveness of the SPRINT PNS System outside the scope of the indication for use statement is unknown.

### 2.2) When the Device should not be used (Contraindications)

Use of the SPRINT® PNS System is contraindicated for:

- Lead placement over the heart or across the thoracic volume.
- Lead placement in the front or side of the neck.
- Lead placement on the top of the head.
- Patients who have a Deep Brain Stimulation (DBS) system.
- Patients who have an implanted active cardiac implant (e.g. pacemaker or defibrillator)
- Patients who have any other implantable neuro-stimulator whose stimulus current pathway may overlap with that of the SPRINT System.
- Patients who require Magnetic Resonance Imaging (MRI). The SPRINT® MicroLead and other SPRINT components must be removed from the body before an MRI.
- Patients who have epilepsy, if the Leads are intended to be placed in the head or neck.
- Patients who have a tape or adhesive allergy.



### 2.3) Warnings, Precautions, & Risks

#### **Risk – a possible side effect of the treatment.**

The following are some of the risks associated with use of the SPRINT System. See Warnings and Precautions sections for additional risks. If you have any side effects or problems with the device, stop use and call your provider.

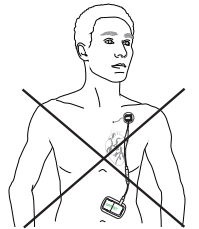
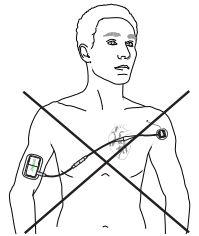
#### **Warning (⚠) – Describes an action or situation that could harm you or your caregiver.**

This section lists potential hazards associated with the SPRINT System that you must be aware of to avoid serious outcomes that may cause injury.



#### **SPRINT Mounting Pad Placement**

- **Do not place the SPRINT® Mounting Pad on the head or the front of the throat.** Placement of the Mounting Pad on head or front of the throat may cause severe muscle spasms resulting in closure of the airway, difficulty breathing, or adverse effects on heart rhythm or blood pressure.
- **The line between the Mounting Pad and the tip of the MicroLead must not cross the heart; electrical current across the heart may cause rhythm disturbances, which could be lethal.**
- **Mounting Pads should only be placed on clean, healthy skin.** Placement on unhealthy skin (for example, injured skin, or rashes) may further irritate the area and cause discomfort. It is okay to apply the Pad to a birthmark or hair bearing areas. If you experience sensitivity or the pad does not stick well, move the Pad to another location.



**Do not leave a child or pet unattended with System components** – Entanglement may result in strangulation and small parts may present a choking hazard.



**Routinely inspect your skin** – Inspect your skin for signs of infection, nerve, or blood vessel damage. If you notice signs of redness, itching, swelling, or bruising near your MicroLead exit site, Mounting Pad, or Cradle, call your provider.











**Do not connect any part of the SPRINT System which is touching or connected to your body to any power source (such as a wall outlet). This could cause serious injury or death.**



**Operation of heavy machinery (driving, etc.)** – Do not use the System while driving, operating machinery, or during any activity in which involuntary (not under your own control) muscle tension may put you at risk of injury.



**Pregnancy** – Safety for use during pregnancy has not been established.

-  **Diathermy** – Do not have diathermy anywhere on your body while MicroLeads are in place. Diathermy is a medical treatment applied to the outside of the body that delivers heat into the body. Heat from diathermy can be transferred to your Leads and can cause tissue damage and possibly severe injury. Diathermy can also damage your Pulse Generator and Mounting Pad. Serious burns of the skin and tissue under the Mounting Pad may occur.
-  **Disinfecting the SPRINT System** – Disinfect your System before and after entering a hospital, clinic, or medical office. Follow your healthcare provider's guidance. Keep your System clean and avoid contact with unclean areas and pests. Dispose of any used Mounting Pads when entering or leaving a hospital, clinic, or medical office. See Chapter 5 – Cleaning & Care for more information.
-  **The SPRINT System contains magnets that might interfere with active implantable medical devices in individuals that come in close contact with you.** To avoid any potential interactions, keep SPRINT components away (more than 6 inches/15 centimeters apart) from individuals who have these devices. Individuals should consult with their physician and medical device manufacturer for specific guidelines.
-  **Stimulation sensation while walking** – Use caution while walking if receiving stimulation in your legs until you feel comfortable with how your treatment feels.
-  **MicroLead Connector and Mounting Cradle Placement** – To reduce the risk of infection, do not place the Connector or the Cradle directly on top of the Lead exit site.
-  **Painful stimulation** – If stimulation is painful, turn stimulation down. If stimulation is still painful, turn stimulation OFF. Tell your provider that the stimulation is painful. If you are unable to turn stimulation off, remove the Pulse Generator from the Mounting Pad or unplug the cables from the Pulse Generator.
-  **Other medical conditions** – Follow your provider's instructions if you have suspected or diagnosed heart disease, or epilepsy. If you tend to bleed internally (or you take medications that make your blood thinner), or if you are receiving stimulation near a surgical site, notify your provider.
-  **Electronic medical equipment** – The Pulse Generator may interfere with patient monitoring equipment or other medical tools. Before any medical tests or procedures, ask your provider if the procedure might harm your SPRINT System. Always turn off and disconnect your System before any tests or procedures begin.



**Electromagnetic Interference (EMI)** – The System is not likely to cause any interference to other equipment other than possible Bluetooth interactions.

- **System interference with nearby devices:** The SPRINT System may interfere with nearby RF devices (radios, TVs, cell phones, smart watches). The System uses Bluetooth wireless communication in the Pulse Generator and Remote. Too many Bluetooth devices in use at one time can disrupt one or more of the devices.
  - If moving away from another device solves the problem, it is likely that the System is interfering with the other device. Move so that your SPRINT System does not interfere with the other device.
- For more details on EMI, contact Customer Service (see Appendix E: Contacting Customer Service).



**Nearby device interference with the System:** The SPRINT System may be disrupted by other RF devices (radios, TVs, cell phones, smart watches).

- Disruptions are most likely to cause an inability to use the Remote to control the Pulse Generator, or temporary changes to stimulation. Stimulation turning OFF is also a possibility.
- Portable RF equipment (especially cell phones) should not be used closer than 30cm (12 inches) to the Pulse Generator or Remote to avoid disruption of the SPRINT System. If disruption occurs, there is no risk of injury.
- Stimulation can always be turned OFF by pressing the button on the Pulse Generator, removing the Pulse Generator from the Pad, or by unplugging the cables.



**Note (FCC Compliance)** – This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.


- Changes or modifications made to the System or System components not expressly approved by SPR Therapeutics will void the authority to operate the System.
- The FCC ID of the Hand-Held Remote (2AO2X-9620) is displayed on the initial splash screen after being unlocked. The FCC ID of the Pulse Generator (2AO2X-9610) is located on the label on the back the device.





**Handle the SPRINT System with care** – Be careful when handling. Dropping or crushing can damage your System.



**The SPRINT System is not water proof** – The Pulse Generator and Hand-Held Remote are rated for IP22 (protected from touching internal components with a finger and from dripping water). Do not submerge the System in water, alcohol, other fluids, or dust. Exposure to fluids (like water) or dust could damage the System. This may cause it to stop working or produce discomfort. Note: adding a drop of water to the sticky side of the Pad before use to improve stickiness is okay.

 **Battery care** – The batteries may become unsafe if taken apart. They may short when battery connections contact metal or when exposed to high heat or fire. The materials in the battery can discolor skin and are not safe to ingest. Do not leave the System in a closed vehicle in hot temperatures.

 **The Lead may break beneath your skin either during your treatment or during removal. In most instances, the Lead remnant does not need to be removed. However, it is possible that an infection may occur. If signs of infection occur, call your provider.**

 **Your skin could become irritated while using the Mounting Pad, Cradle, or Bandages. Check your skin for irritation. Some redness is normal. To minimize irritation, refer to Chapter 5: Cleaning & Care.**

### Precaution – Information on how to prevent damage to or failure of your device.

This section lists instructions you should follow to avoid situations that may cause discomfort or damage your System.

**Do not take apart or modify any part of the SPRINT System** – Doing so may cause injury to you or damage to your System.

**The SPRINT System is Magnetic Resonance (MR) unsafe** – All the MRI procedures anywhere on your body are not allowed while you are using the SPRINT System. Having an MRI procedure can cause tissue heating, injury, or unwanted stimulation. A medical professional should pull out the Lead and remove all other System parts before an MRI is conducted. If a Lead breaks and a piece of the Lead remains under your skin, it is safe to receive an MRI under the conditions described in Appendix F.



**A retained Lead remnant ONLY is MR conditional** – If a piece of the Lead remains under your skin after Lead removal, you can be scanned safely in an MR system under conditions described in Appendix F.



**Do not use any piece of the SPRINT System with a component that is not part of the System** – Doing so may cause injury to you or damage to your System.

**MicroLead dislodgement or fracture** – Avoid pulling on the MicroLead or anything connected to it. This may cause the MicroLead to be pulled out or to fracture. A change in how your treatment feels may mean that the Lead has moved. If your treatment becomes painful, stop using your System and call your provider. Limit strenuous physical activity and motion (such as twisting, bending, climbing, lifting) near the implant for at least one week. Avoid excessive stress (tugging, pressure, heat) that may damage your System.

**Broken or disconnected cable** – If a cable breaks or becomes disconnected, stop stimulation and replace the broken component or reconnect the components, as applicable. A broken or disconnected cable may deliver a safe but uncomfortable stimulation for a few seconds.

**Theft and metal detectors** – Theft and metal detectors found in places like libraries and stores may temporarily interfere with your SPRINT System. They will not damage your System. Walk through and do not stay near the theft or metal detector longer than needed.

**Portable and mobile Radio Frequency (RF) communications** – Portable and mobile Radio Frequency (RF) equipment can interfere with the System. Do not use this equipment while using the SPRINT System.

**Pulse Generator may get warm** – The outside surfaces of the Pulse Generator may become warm to the touch during use (2.4°C [4.3°F] above ambient temperature). This warming is normal and does not represent a problem with the device or its settings. Should the Pulse Generator become uncomfortably warm, stop the stimulation and wait for it to cool, or move it to a nearby location where it is covered less by clothing or better able to remain cool.

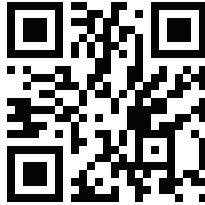
**Long term effects** – The long-term effects of stimulation are unknown.

Skin irritation, infection, or mild tissue inflammation may occur at the Lead exit site.

Stimulation may be uncomfortable at high levels. If uncomfortable or painful stimulation occurs, decrease the intensity or turn off stimulation and call your provider.

**There are no user serviceable parts in the SPRINT System.**

## Patient Instructional Videos



Scan this QR code with a smart phone camera or visit:  
[sprtherapeutics.com/patients/patient-resources/](https://sprtherapeutics.com/patients/patient-resources/)



# QUICK REFERENCE SECTION




## 3 USING YOUR SPRINT® PNS SYSTEM

### 3.1) Start and Stop Stimulation

#### Using Your Hand-Held Remote

To turn stimulation ON with your Remote, press the **middle power** button (the button above the  $\Phi$  symbol).

The  icon will appear and begin flashing, to show that stimulation is ON. The Pulse Generator light will briefly flash green when stimulation is turned ON.

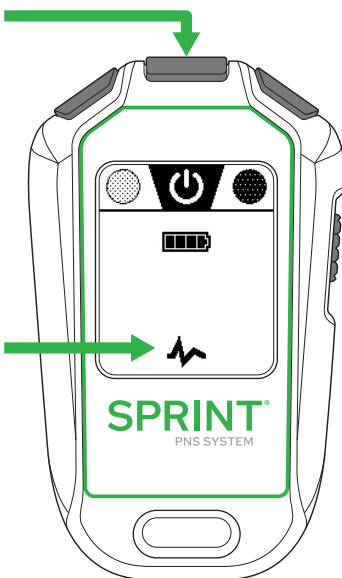
The timer on the screen (if shown) is the treatment session time left (see Chapter 7: Timed/Session Treatment vs Continuous Treatment).

To turn stimulation OFF with your Remote, press the  $\Phi$  button.

OFF will appear on the home screen, to show that stimulation is turned OFF.

Middle Power Button:  
Start / Stop Stimulation

Stimulation  
'ON' Icon



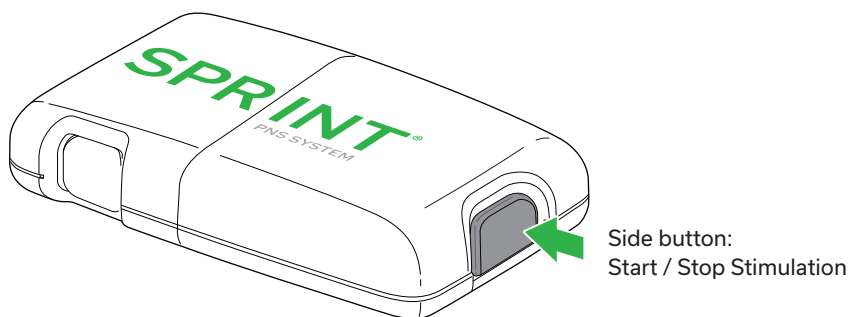
Hand-Held Remote



### 3.2) Using Your Pulse Generator

You can also start and stop stimulation from your Pulse Generator by pressing the side button. The light under the button will turn green when turned ON or OFF.

You will not be able to turn stimulation ON using the side button if your Hand-Held Remote is being used.



**Pulse Generator  
(and Rechargeable Battery)**

### 3.3) Operating Your Hand-Held Remote

#### To unlock your Remote

Move the Lock/Unlock Switch to the up position.

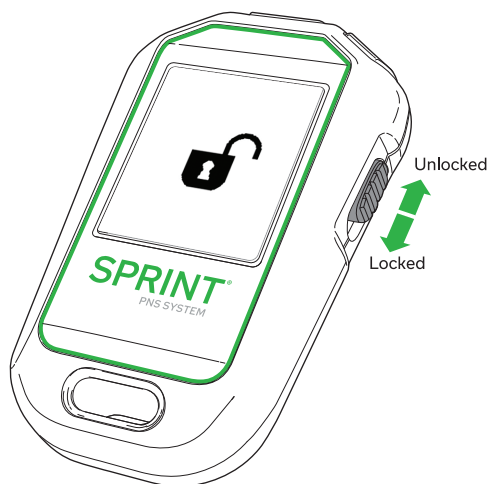
#### To lock your Remote

Move the Lock/Unlock Switch to the down position.

#### To wake up your Remote

Your Remote will go to sleep after a period of inactivity. To wake up the Remote, press any button or move the Lock/Unlock Switch to the Up/Unlocked position.

Hand-Held Remote



The startup screen will show for a few seconds while the Remote connects to the Pulse Generator.

**SPRINT**  
PNS SYSTEM

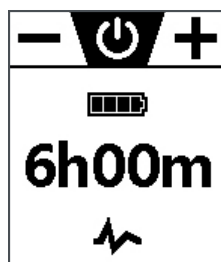
**5043 v1.2.0**

FCC ID: 2A02X-9620

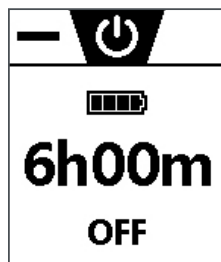
### 3.4) Home Screens: ON and OFF for Each System Configuration

#### Example: Single-Lead System (timed session)

Stimulation ON. Timed session. Countdown timer displayed and counting down.

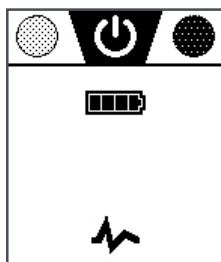


Stimulation OFF. Timed session. Countdown timer displayed, but paused.

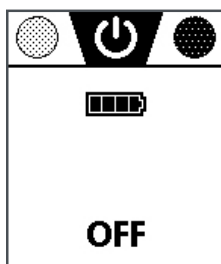


### Example: Dual-Lead System (continuous treatment)

Stimulation ON for both Leads. Continuous treatment. No countdown timer.

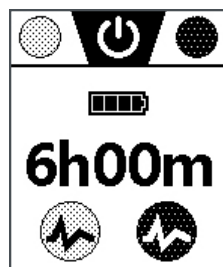


Stimulation OFF for both Leads. Continuous treatment. No countdown timer.

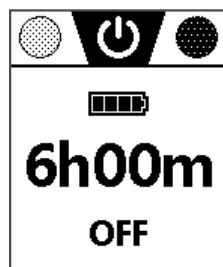


### Example: Dual-Lead, Bimodal™ System (Light Lead on a timed session)

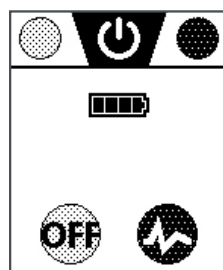
Stimulation ON for both Leads. Timed session. Countdown timer displayed and counting down.



Stimulation OFF for both Leads. Timed session. Countdown timer displayed, but paused.



Timed session expired for Light Lead.  
Stimulation OFF. (OFF).

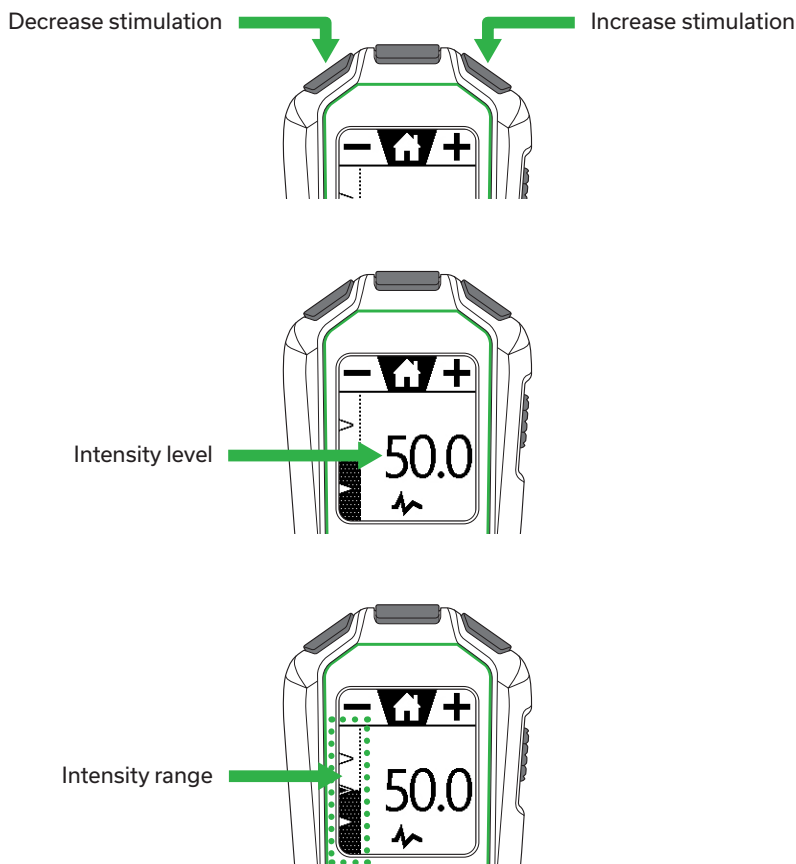


Stimulation still ON for Dark Lead. Continuous treatment. No Countdown timer.


### 3.5) Adjusting Stimulation

The intensity of each Lead may be adjusted independently. You cannot increase stimulation intensity when stimulation is OFF.

**Single-Lead Systems:** Press the [+] or [-] buttons. The [+] is not present when stimulation is OFF.

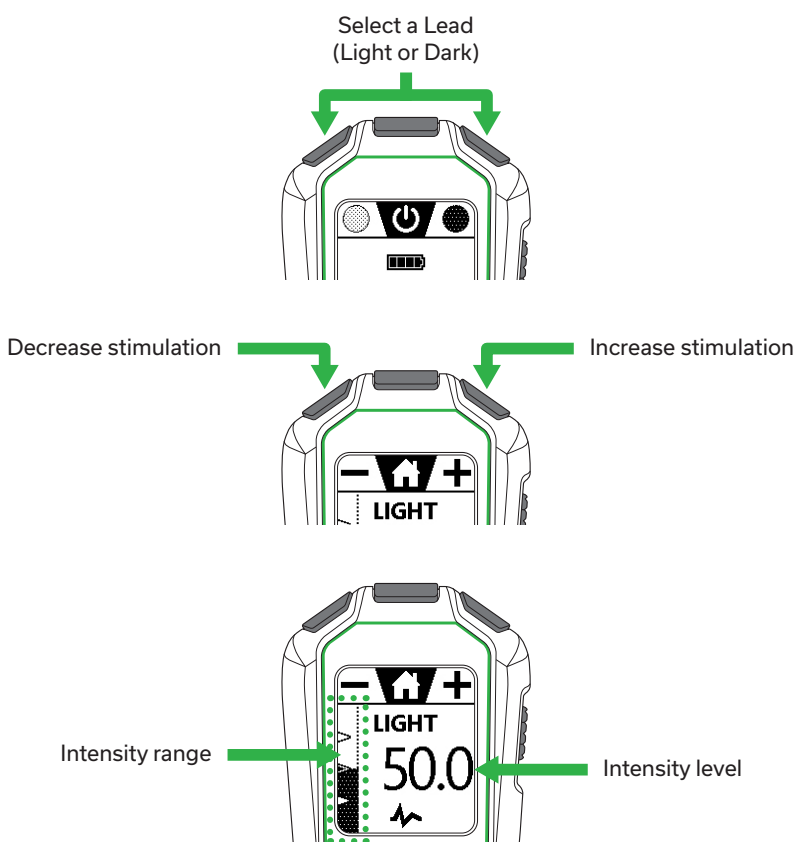


The screen will display the new intensity level. The bar on the side of the screen indicates the intensity level within the minimum and maximum range set by your provider (optional).


To turn stimulation ON or OFF, press the  button to return to the home screen.

**Dual-Lead Systems:** To adjust stimulation, first select a MicroLead by selecting the Light ☉ button or Dark ● button corresponding to the Lead you would like to adjust. Note: when stimulation is OFF, you can only decrease stimulation.

(Holding [+] or [-] buttons will cause the intensity to increase or decrease as long as you hold the button.)



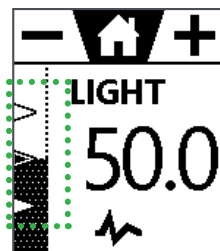
The screen will display the new intensity level. The bar on the side of the screen indicates the intensity level within the minimum and maximum range set by your provider (optional).

To turn stimulation ON or OFF, or adjust the second MicroLead, press the  button to return to the home screen.

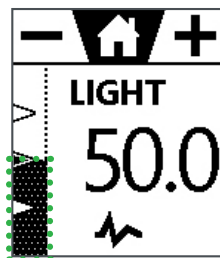
## Selecting a Favorite

Some providers may choose to pre-set stimulation intensity settings (favorites). If set by the provider, the favorites allow you to move directly to these preset values and you will see small triangles on the left-hand side of the screen.

To move directly to the next highest preset value, press and hold the + button and then press the – button at the same time.



To move directly to the next lowest preset value, press and hold the – button and then press the + button at the same time.





## 4 CONNECTING & DISCONNECTING THE SYSTEM

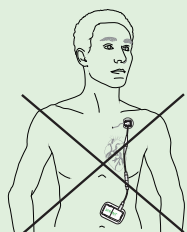
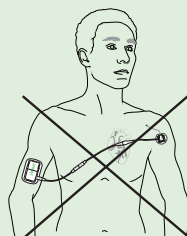
### 4.1) Connecting the System

1. Prepare the Mounting Pad Placement Site
  - Clean the areas, clipping (not shaving) hair as needed
  - Skin oils may be removed by wiping skin with rubbing alcohol

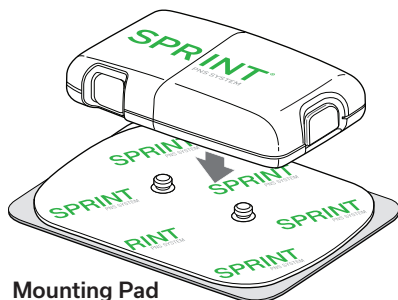
**!** The line between the Mounting Pad and the tip of the MicroLead must not cross the heart; electrical current across the heart may cause rhythm disturbances, which could be lethal.

**!** Do not place the SPRINT Mounting Pad on the head or on the front of the throat. Placement of the Mounting Pad on head or front of the throat may cause severe muscle spasms resulting in closure of the airway, difficulty breathing, or adverse effects on heart rhythm or blood pressure.

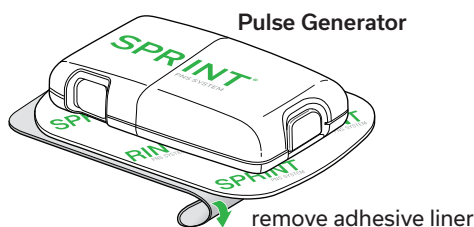
**!** Mounting Pads should only be placed on clean, healthy skin. Placement on unhealthy skin (i.e., irritated or injured skin, rashes or wounds) may further irritate the area and cause stimulation to feel different or be uncomfortable. It is acceptable to apply the Mounting Pad to a birthmark and hair bearing areas. If the patient experiences sensitivity or poor adhesion, move the Mounting Pad to another location.



2. Snap the Pulse Generator onto the Mounting Pad.



3. Slowly remove Mounting Pad from the clear adhesive liner.



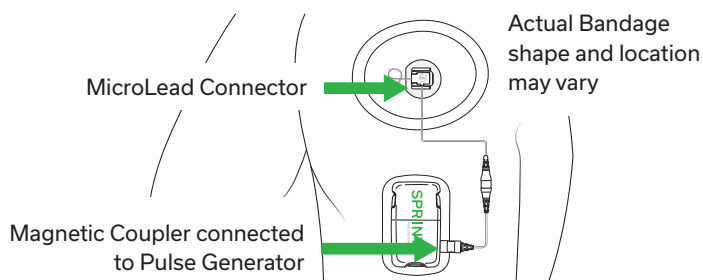
4. Place the Pad with the Pulse Generator in the location advised by your provider.
  - Be sure the Pad location does not put tension on your MicroLead Connector.
  - Make sure the entire Pad surface is stuck to your skin.



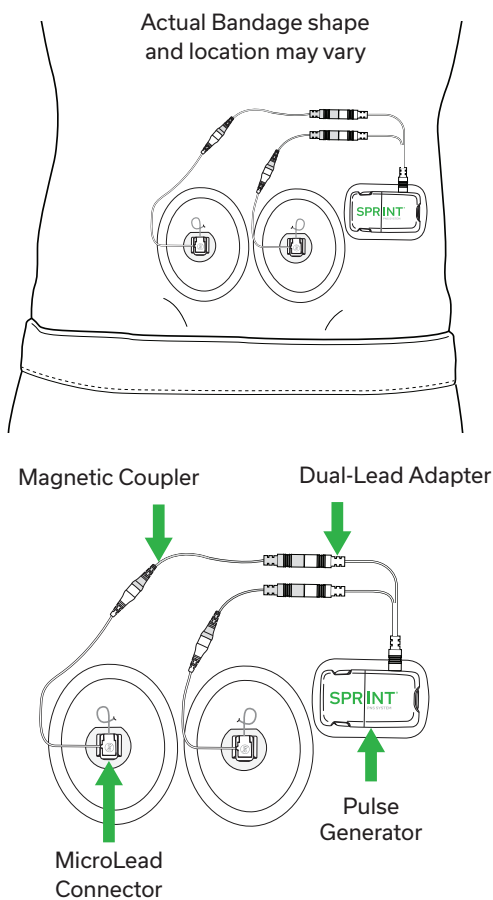
**NOTE:** If the Pad does not stick well, add a drop of tap water to the sticky (gel) side prior to use. Replace with a new Pad when needed.

5. Connect the Pulse Generator to the Magnetic Coupler. Depending on the location and type of System this may include connecting extension cable(s) and a Dual-Lead Adapter (Dual-Lead Systems only).
6. Connect Magnetic Coupler(s) to the MicroLead Connector(s). When connecting a Dual-Lead System, The Light Coupler will only connect with the Light MicroLead Connector, the Dark Coupler will only connect with the Dark MicroLead Connector. Use short or long extension(s) as needed.

## Single-Lead System – Connected



## Dual-Lead System – Connected



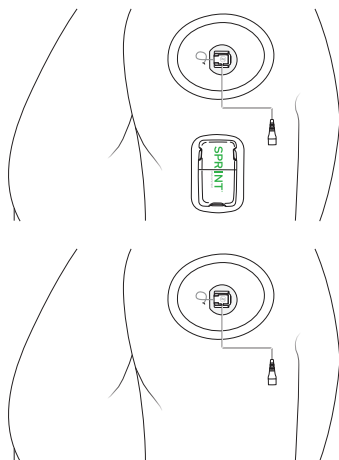
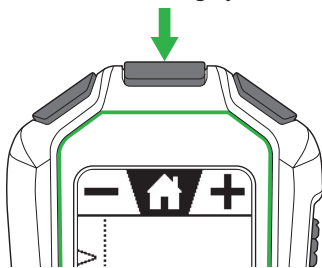
## 4.2) Disconnecting the System

**To disconnect your System before showering or when treatment is OFF**

1. Turn stimulation OFF using the Remote or Pulse Generator. The home screen will display OFF showing that your Pulse Generator is no longer delivering stimulation. (see Section 3.1: Start and Stop Stimulation)
2. Disconnect the MicroLead Connectors from the Magnetic Couplers.
3. Unsnap the Pulse Generator from the Mounting Pad.
4. Remove the Mounting Pad by slowly peeling it off your skin. Return the Mounting Pad to its liner if it will be reused.

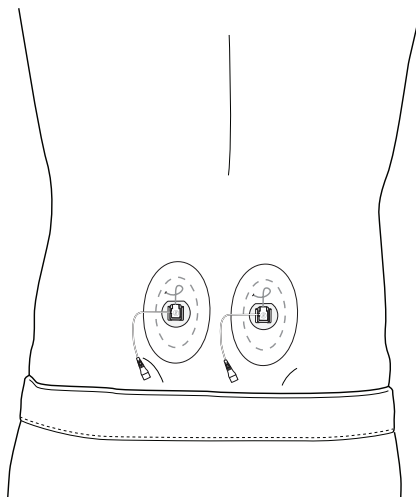
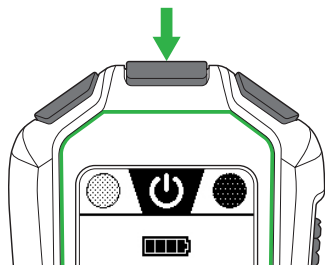
### Single-Lead System – Disconnected

Turn stimulation OFF prior to disconnecting System



## Dual-Lead System – Disconnected

Turn stimulation OFF prior to  
disconnecting System



## 5 CLEANING & CARE

Your provider will show you how to care for your skin and Lead exit sites (where the MicroLead goes through your skin). They will also discuss how and when to change the Waterproof Bandages and Mounting Cradles.

### 5.1) Caring for the MicroLead Exit Site(s)

It is very important that you keep your exit site(s) clean and dry at all times.

**To keep your skin healthy and minimize risk for infection, follow these instructions:**

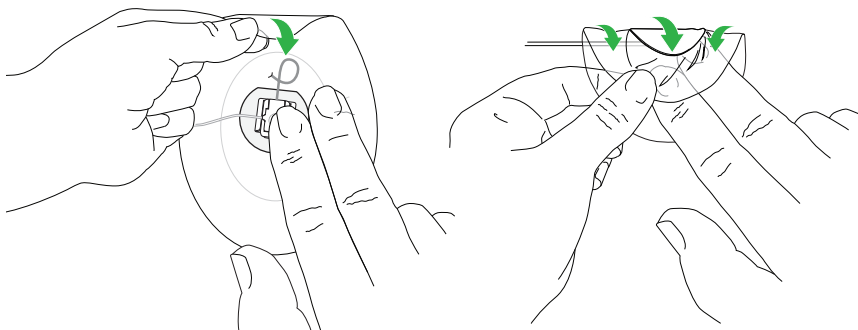
- Keep the exit site(s) clean and dry.
- Use Bandages to cover the exit site(s) and MicroLead Connector(s).
- Never soak exit site(s) in water. It is okay to shower with Bandages in place over the exit site(s).
- Before placing the Pads, Cradles, or Bandages, wash the area of skin with soap and water. Allow to dry.
- Skin oils may be removed by wiping skin with rubbing alcohol.
- Change your Mounting Pad, Cradle(s), and Bandage(s) as necessary.
  - Mounting Pads should be changed daily or as needed.
  - Cradles and Bandages should be changed weekly or as needed.

## 5.2) Changing the Waterproof Bandage(s) and Mounting Cradle(s)

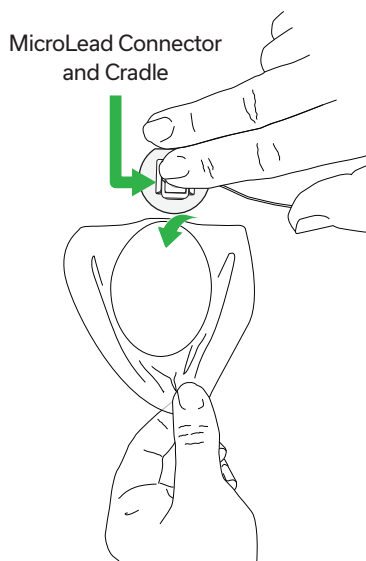
If the Waterproof Bandage(s) or Mounting Cradle(s) are soiled, damp, or starting to peel, they must be replaced.

**Follow these instructions to replace:**

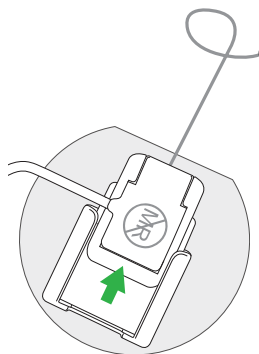
1. Wash your hands.
2. Hold the Connector stable while peeling off the old Bandage.



Bandage shape may vary



3. Wash your hands again.
4. Clean the exit site with soap and water. Allow to dry.
5. Check if the Cradle(s) need to be replaced.
  - If so, slide the Connector out of the Cradle. Avoid pulling on the MicroLead.

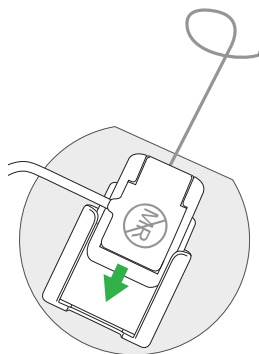


- Peel off the Cradle and replace it with a new one.  
**Do not place the MicroLead Connector or the Mounting Cradle directly on top of the MicroLead exit site.**

**⚠ Warning!**

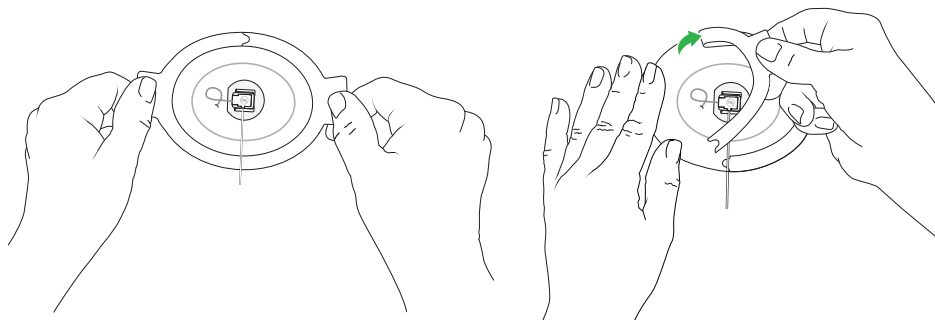
To reduce the risk of infection, do not place the MicroLead Connector or the Mounting Cradle directly on top of the MicroLead exit site.

- Slide the Connector (with the MR symbol facing up) into the Cradle.

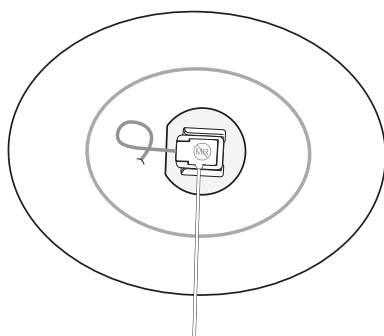




6. Place the center of the new Bandage over the MicroLead exit site. Make sure that no portion of the Bandage adhesive touches the MicroLead, MicroLead exit site or Connector.



7. Press the sticky edges of the Bandage firmly onto your skin so no water can enter the MicroLead exit site. The Connector cable will pass underneath the edge of the Bandage. (see Section 4.1: Connecting the System)



Do not let the adhesive portion of the Bandage touch the MicroLead exit site or the MicroLead Connector. This could result in the MicroLead being pulled out.

### 5.3) System Cleaning

**Clean your System as needed. Also clean it before and after entering a hospital, clinic, or medical office.**

- Use a soft cloth. Dampen the cloth with soapy water to wipe down the Pulse Generator or cables.
- Do not submerge the Pulse Generator or allow the cables to become wet.
- If the Pulse Generator or cables become wet, dry them off before use.
- Your provider may give you special instructions on how to clean your System.
- Dispose of any used Mounting Pads when entering or leaving a hospital, clinic, or medical office.

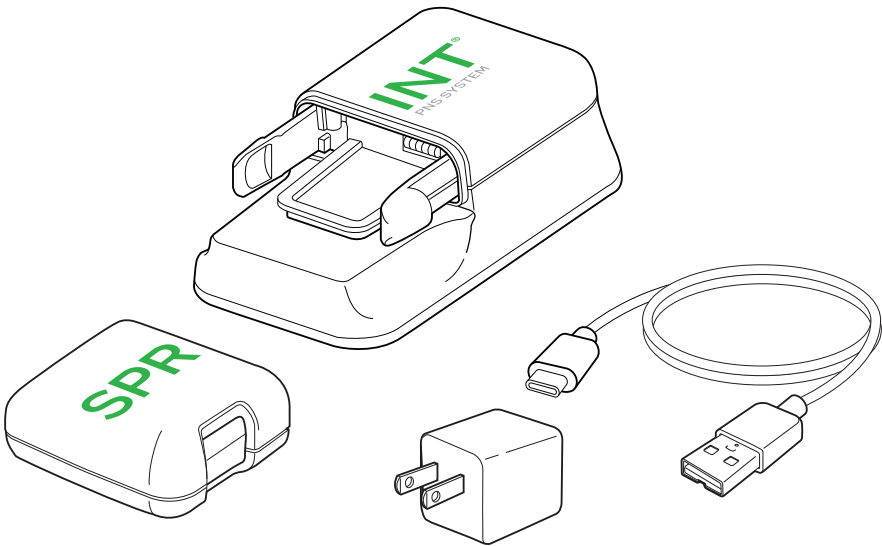
### 5.4) Disposal

Disposal of all System parts must comply with national, state, and local laws governing the disposal of such items.

Rechargeable Batteries and the Remote must never be disposed of in a fire because they contain batteries.


## 6 BATTERY & CHARGING YOUR SYSTEM

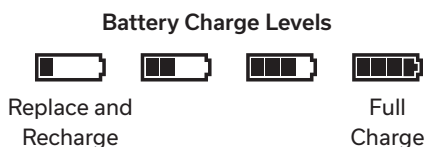
Your System has two Rechargeable Batteries, a Recharging Base, and Recharging Base Power Supply. How often you need to charge your battery depends on your stimulation intensity and how often you use the System.



**NOTE:** When you first bring your System home, put the spare battery in the Recharging Base to charge. Always have one battery charging so that you never miss your daily treatment.

## 6.1) Checking the Rechargeable Battery Level

To check your battery charge level, unlock your Remote by moving the Lock/Unlock Switch to the Up/Unlocked position (see Section 3.3: Operating Your Hand-Held Remote). The home screen will display the battery charge level icon .

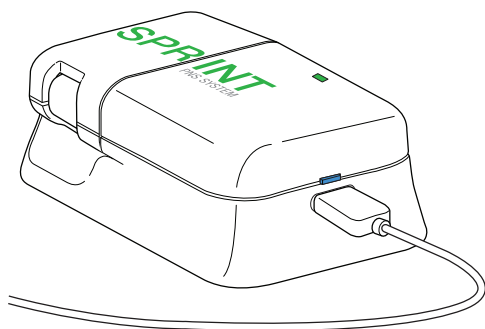





When your battery is fully charged, the icon will show either three or four bars. Recharge your battery when the icon shows one bar. Your Remote may display a message stating "Recharge Battery" when your battery charge is low. The Pulse Generator will also emit tones (3 short beeps) and will flash yellow when your battery is low.

## 6.2) Charging the Battery

### To recharge a used battery:

1. Plug the Recharging Base Power Supply into a wall outlet.
2. Slide the used battery into the Recharging Base until the battery clicks into place. Connect the Power Supply to the Recharging Base.
3. When the Base is plugged in, the power LED located above the cable will turn blue.
4. When the battery is charging, the battery charge level LED on the top of the Base will flash green.
5. Once the battery is fully charged, the battery charge level LED will turn solid green. If LED is yellow, refer to troubleshooting. (Appendix B)

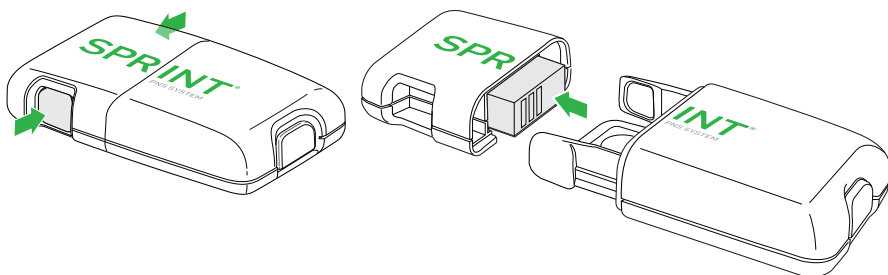


-  Charging: Flashes green
-  Charge complete: Solid green
-  Charge error: Solid yellow

### 6.3) Removing / Changing the Battery

**To remove a battery from the Pulse Generator:** Pinch the tabs on both sides of the Pulse Generator until the battery releases. Slide the battery out.

Press tabs to open



**To insert a battery into the Pulse Generator:** Slide the battery into the Pulse Generator until it clicks into place. Once inserted, you will hear a short beep and a light to show the charge level of the battery (as shown below).

Light Displayed	Associated Battery Charge Level
5 second Green light	Partial to Full charge
5 second Yellow light	Low charge
Flashing Yellow light	Critically Low charge; Replace and recharge the Rechargeable Battery

## 7 TIMED/SESSION TREATMENT vs CONTINUOUS TREATMENT

### 7.1) Your Treatment Type

Your provider will prescribe either 24 hour Continuous Treatment or Session Treatment.

#### 24 hour Continuous Treatment

If you have 24 hour Treatment, you should have stimulation on all day and night. You should only stop and disconnect your System when you need to shower, change Bandages or when a warning or precaution applies. (For example, do not have treatment on while operating heavy machinery; see Chapter 2: Important Safeguards for more information.)


#### Session Treatment

If you have Session Treatment, you should have stimulation on for the programmed number of hours each day. The number of hours can range from 1 to 24 hours (independent of stimulus frequency). Only the clinician can adjust the number of hours your Pulse Generator is programmed to deliver stimulation. Your Remote will keep track of how long stimulation has been on using a timer (see Section 7.2: Session Countdown Timer).

## 7.2) Session Countdown Timer (only applicable to timed session configurations)

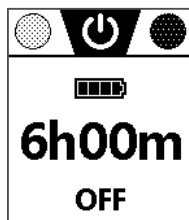
### Using Your Hand-Held Remote

Session Treatment is where your clinician programs your stimulation to turn OFF after a certain number of hours (default six). If you have been prescribed Session Treatment, your Remote home screen will show a countdown timer once stimulation has been turned on. Patients with Continuous Treatment (24 hour) will not see a timer.

Once stimulation has been turned on, the  icon will appear and begin flashing and the countdown timer will begin counting down from the number of hours programmed.



If you stop (pause) stimulation during your session, the home screen will display the amount of time you have left to complete.



After being OFF for more than 2 hours, the Remote will ask if you would like to continue the current session. Press the "Con" button to continue the current session or press the "New" button to start a new session.

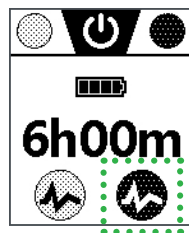


\* If OFF for more than 12 hours, the countdown timer will reset to the full session time.

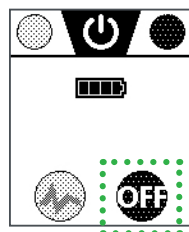


### 7.3) Bimodal™ Systems Only (only applicable to certain Dual-Lead Systems)

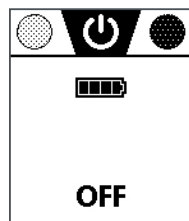
**Bimodal Systems only:** one Lead will have a countdown timer, while the other will be continuous (by default). In the example to the right, the Dark Lead is timed (green outline). When a timed session on one Lead has completed, you will have the option to start one or both Leads, as shown in the following steps.



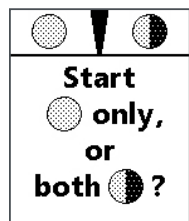
Timed session has concluded denoted by **OFF**. To restart a session press the **⏻** button.



The first press will stop all stimulation. Press the **⏻** button a second time to select stimulation.



The second press will prompt starting a Single-Lead (untimed) **⦿**, or both, Timed and Untimed **◐**. Light or Dark indicator may vary based on how your System was configured.



## FREQUENTLY ASKED QUESTIONS

### If you have more questions, call your provider

#### **Can I shower?**

Disconnect the System as described in Section 4.2: Disconnecting the System. Continue to use the Waterproof Bandages to keep the exit site areas, including the MicroLead Connectors, dry during showering.

#### **Can I take a bath? Can I swim?**

Do not take a bath or swim. Do not soak the exit sites in water.

#### **Can I walk with stimulation on?**

Use caution while walking if receiving stimulation in your legs until you feel comfortable with how your treatment feels.

#### **Can I drive while using the System?**

Do not use the System while driving, operating machinery, or during any activity in which involuntary (not under your own control) muscle tension may put you at risk of injury.

#### **Can I travel on an airplane with the System?**


The System includes small lithium batteries. Follow all Federal Aviation Administration (FAA) regulations or other international regulations for the storage and packing of lithium batteries in carry-on bags when flying with your System.

**SPRINT® PNS System may set off airport security systems. To avoid major delays or problems, bring your Instructions for Use which explains the purpose and nature of the System.**

#### **How much (how many hours per day) should I use stimulation?**

Your provider will prescribe the amount of treatment you should receive every day.

#### **How do I know stimulation is working?**

When stimulation is on, the  icon will be pulsing on the home screen of the Remote.

#### **Do I have to remember to turn stimulation OFF?**

No. If a session is less than 24 hours, stimulation will stop automatically at the end of the session. For 24 hour treatment, stimulation is left on except for showering, battery changes, or Bandage changes.

#### **What do I do if I lose or run out of a part?**

Call your provider (or SPR Representative if you have been assigned one) to request replacement parts.

#### **Can I take the MicroLeads out myself?**

No, the MicroLeads must be removed by your provider.

#### **How often do I change the Rechargeable Battery?**

It will depend on the intensity of the stimulation you receive. Check your battery charge icon and replace and recharge the batteries as needed (approximately daily).

#### **How do I increase or decrease stimulation intensity?**

See Section 3.5: Adjusting Stimulation.

#### **Can I exercise while using the System?**





Limit activity & motion for at least one week. You may resume exercise or treatment when directed by your provider.

## TROUBLESHOOTING

If you have more questions, call your provider (or SPR Therapeutics Representative if you have been assigned one).

### Problem: "Lead Connect Error"

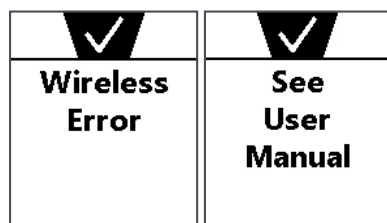
Examples below may vary based on your configuration

Single-Lead System		
Single-Lead System – Treatment is not able to be properly delivered	<div>Lead Connect Error</div>	<div> <div>Yes</div> <div>No</div> <div>Check Pad and Cables. Retry?</div> </div>
	FOLLOWED BY	
Dual-Lead System		
Dual-Lead System – Treatment on the Light Lead is not able to be properly delivered	<div>Lead Connect Error</div> <div></div>	<div> <div>Yes</div> <div>No</div> <div>Check Pad and Cables. Retry?</div> </div>
	FOLLOWED BY	
Dual-Lead System – Treatment on the Dark Lead is not able to be properly delivered	<div>Lead Connect Error</div> <div></div>	<div> <div>Yes</div> <div>No</div> <div>Check Pad and Cables. Retry?</div> </div>
	FOLLOWED BY	
Dual-Lead System – Both Leads are not properly connected	<div>Lead Connect Error</div> <div></div> <div></div>	<div> <div>Yes</div> <div>No</div> <div>Check Pad and Cables. Retry?</div> </div>
	FOLLOWED BY	

### Actions to be taken in order

1. Confirm that the Hand-Held Remote screen says, "Lead Connect Error; Check Pad and Cables. Retry?"
2. Confirm that all plugs (cable connections) are securely connected. If you have a Dual-Lead device and there is an error on ONLY one Lead, the connection issue is likely between the MicroLead and the Dual-Lead Adapter. If there is an error on both Leads or you have a Single-Lead device ensure your Mounting Pad is correctly attached to patient skin AND correctly attached to the Pulse Generator.
3. Replace the Mounting Pad and place on clean & dry skin.
4. Check magnetic connection points of the Magnetic Coupler and MicroLead Connector.
  - If connection points aren't clean and shiny, call your provider.
5. Remove any extension cables between the Magnetic Coupler and Pulse Generator.

### Problem: Wireless Error





### Actions to be taken in order

1. Confirm that Hand-Held Remote screen says, "Wireless Error".
2. Place the Hand-Held Remote within arm's length, and make sure the Remote has a clear 'line of sight' to the Pulse Generator.
3. Press the middle button on the Hand-Held Remote.
4. Move the "lock/unlock" switch to the "locked" position and wait for the screen to go blank before unlocking again.
5. While the Hand-Held Remote is locked, remove the Rechargeable Battery from the Pulse Generator and reinsert. Wait at least 5 seconds after the Pulse Generator's green light and audible beep.

6. Hold the Hand-Held Remote so that there is little or no body tissue between the Hand-Held Remote and the Pulse Generator and then move the "lock/unlock" switch to the "unlocked position". It may be necessary to hold the Remote in this position each time a button on the Remote is pressed (although the Remote can be moved to a more convenient location 1 second after the button push to allow easier viewing of the Remote's screen).
7. If it is difficult holding the Hand-Held Remote in a location where there is not significant body tissue between the Remote and Pulse Generator, it may be necessary to reposition the Pulse Generator and Mounting pad to a location that allows the Remote to have a straight 'line of sight' to the Pulse Generator.

**Problem: "Internal Error"**

	
<b>Internal Error</b>	<b>See User Manual</b>

**Actions to be taken in order: Test stimulation between each step as appropriate**

1. Confirm Hand-Held Remote Screen says, "Internal Error".
2. Remove the Rechargeable Battery from the Pulse Generator and reinsert.
3. Replace the Rechargeable Battery with a new one.

### **Problem: Remote Does Not Power ON or displays "Replace Remote Battery"**

#### **Actions to be taken in order**

1. Confirm the device does not turn on by Locking and Unlocking the Hand-Held Remote.
2. Replace the Coin Cell Battery located within the Hand-Held Remote. A small Phillips head screwdriver and CR2032 Lithium Coin Cell Battery are required.

To access the Coin Cell Battery:

- Lock the Remote.
- Peel up the label located on the back of the Hand-Held Remote to expose cover screw. Save the label for future reference.
- Gently press the small black retaining tab to remove the battery. (Slight pressure may need to be applied to pop out the battery once the tab is pressed.)
- Insert new coin cell battery with the "+" side facing up.
- Replace the cover and tighten screw until snug.



#### **Warning!**

To reduce the risk of infection, do not place the MicroLead Connector or the Mounting Cradle directly on top of the MicroLead exit site.

**Warning:** the coin cell battery is a swallow hazard for infants and small children; dispose of promptly. Disposal must comply with national, state and local laws governing the disposal of such items.

### **Problem: Mounting Pad is Not Adhering to Skin**

#### **The following steps may be recommended**

1. Clean skin with mild soap and water and allow skin to dry.
2. Wipe skin with an alcohol pad and allow skin to dry.
3. Apply a drop of tap water to adhesive side of the Mounting Pad.
4. Change Mounting Pad regularly.
5. Hold Pulse Generator and Mounting Pad in place (e.g., ACE Bandage Wrap).
6. Ask your provider about skin prep products.

**Problem: Skin Irritation – Mounting Pad**

**The following steps may be recommended**

1. Regularly change the location of the Mounting Pad on skin.
2. Ask your provider about using skin prep wipes prior to the application of the Mounting Pad.
3. Ask your provider about additional topical solutions that may be prescribed for the affected area.


**Problem: Skin Irritation – Bandage**

**Ask your provider about alternative solutions**

**Problem: Skin Irritation – Mounting Cradle**

Adjust the location of the Mounting Cradle. If irritation persists, discontinue use of the Mounting Cradle. To secure the MicroLead Connector in place, continue to cover the Connector and exit site with the non-adhesive portion of the Bandage.

## Additional Troubleshooting Steps:

Problem	Possible Causes	Actions to be Taken
Battery symbol is blinking	Rechargeable Battery is low	Replace and recharge the Battery
Screen shows "Recharge Battery"	Rechargeable Battery is low	Replace and recharge the Battery
Screen shows "Replace Remote Battery" or has a fixed screen and does not respond to button presses	Remote Battery is low	See corresponding trouble shooting section
Session time is not decreasing	Treatment has been paused or was not yet turned ON	Turn treatment on by pressing the  button
Stimulation will not turn ON	Rechargeable Battery is too low	Replace and recharge the Battery
Buttons are not working	Remote is locked	Move switch to unlocked (up) position
Stimulation sensation changes	Mounting Pad in different place than usual	Reposition Mounting Pad
Note that minor changes in sensation with posture are common. Increase or decrease the stimulus intensity if desired	Mounting Pad not sticking to skin well	See troubleshooting section "Mounting Pad is not adhering to skin"
	MicroLead has moved	Call your provider
Pulse Generator not working correctly	Pulse Generator issue	If the Hand-Held Remote displays "Internal Error", "Wireless Error", "Lead Connect Error", "Recharge Battery", or "Replace Remote Battery" see the corresponding troubleshooting section
Stimulation is painful	Pulse Generator issue OR MicroLead has moved	Turn stimulation OFF. If stimulation will not turn off, remove the Rechargeable Battery from the Pulse Generator. Call your provider
Stimulation turns OFF on its own (other than timed stimulation)	Rechargeable Battery is too low	Replace and recharge the Rechargeable Battery
	An error has occurred	Turn stimulation back ON and continue use. If the screen displays an error message, follow directions in the corresponding troubleshooting section
Stimulation turns OFF on its own and cannot be restarted	The end of the maximum treatment duration (60 days) has been reached	Call your provider
Solid Yellow Light on Recharging Base	Defective Battery	Try another Battery or contact customer service for a replacement



## SPECIFICATIONS

All the components of the SPRINT System are suitable for storage and transportation between at least -5°C (23°F) and 45°C (113°F). This includes the products outside their shipping carton as well as the product as stored by the clinician or patient between uses.

Allow components to warm or cool for a minimum of 2 hours before using at typical room temperature of 20°C (68°F) when stored at maximum or minimum storage conditions. Do not store system components in direct sunlight or near heating elements. Too high of temperature or sunlight may dry the Mounting Pad and it may not adhere to the skin.

All the components of the SPRINT System are suitable for use under the following operating conditions:

- a temperature range of 10°C (50°F) to 40°C (104°F);
- a relative humidity range of 15% to 85%, non-condensing, with not more than 50 hPa of water vapor pressure; and
- an atmospheric pressure range of 700 hPa to 1,060 hPa.

### SPRINT MicroLead (REF 80067)

Parameter	Specification
Stimulating electrode of the MicroLead	Length: 1.5 cm Surface area: 10mm <sup>2</sup> (minimum)
Maximum resistance	150 ohms
Sterility	Provided sterile by Ethylene Oxide and non-pyrogenic

### SPRINT Pulse Generator (REF 9610, with Rechargeable Battery: REF 9612)

Parameter	Specification
Dimensions	Approximately 6.2cm x 3.7cm x 1.4cm
Mass	Approximately 30g

## APPENDIX C: SPECIFICATIONS

Parameter	Specification
Controls & Indicators	Control and multicolor Visual Indicator is a Momentary Pushbutton on the side of the Pulse Generator's housing; The Pulse Generator also generates audio attention tones
Wireless Communications	Bluetooth (Low Energy)
Output Control	<ul style="list-style-type: none"> <li>Amplitude range: 0.2mA to 30mA (+/-10% for all Amplitudes above 5.0mA; below 5.0mA, accuracy of total per pulse charge is +/-25%)</li> <li>Frequency range: 5 - 150Hz (+/- 0.5% averaged over 10 pulses; +/- 10% pulse-to-pulse)</li> <li>Pulse duration range: 10<math>\mu</math>s - 200<math>\mu</math>s (+/- 4<math>\mu</math>s; below 2mA, the minimum Pulse Duration is 20<math>\mu</math>s)</li> <li>Duty cycle range: &lt;1% - 100%</li> </ul>
Stimulus Waveform	Asymmetric biphasic, no net DC
Maximum Charge Per Pulse	4 $\mu$ C
Maximum Charge Density at Stimulating Electrode	0.4 $\mu$ C/mm <sup>2</sup> (when in use with the SPRINT MicroLead)
Maximum Current Density at Return Electrode (Pad)	0.19mA/cm <sup>2</sup> (1.2mA/inch <sup>2</sup> )
Range of Load Impedance	200 $\Omega$ to 1,300 $\Omega$
Maximum DC Current Component of Output	<1 $\mu$ A
Rechargeable Battery	240mA-hr Lithium Ion Polymer cell with protective circuitry in protective housings
Time to recharge a fully exhausted Battery	Approximately 4 hours. While charging one of the rechargeable batteries, the Pulse Generator can be powered with the second Rechargeable Battery

Parameter	Specification
Typical Battery Operating Time	Dependent on the stimulus parameters in use; most patients will be able to use the Pulse Generator for 12 to 24 hours on a fully charged Battery; Baseline Operating Life: 24 hours of continuous stimulation with 1- channel stimulating at 100Hz, 20mA, 80 $\mu$ s, 100% duty cycle into a 1,500 $\Omega$ patient circuit resistance
IEC 60601-1 classification and designations	<ul style="list-style-type: none"> <li>– Type BF equipment</li> <li>– Internally powered</li> <li>– NOT suitable for use with flammable anesthetic agents</li> <li>– Suitable for use in the Home Healthcare Environment and the Professional Healthcare Environment</li> </ul>

### SPRINT Recharging Base (REF 9615)

Parameter	Specification
Size	Approximately 7.2cm X 4.2cm X 2.6cm
Mass	Approximately 60g
Controls & Indicators	No controls; two visual indicators; Blue light (next to the receptacle for the USB Power Adapter plug) indicates DC power is being supplied to the unit; The indicator on the top of the housing indicates if the Rechargeable Battery is charging (flashing Green), is fully charged (continuous Green), or is not charging (Yellow)
Charging Protections	Circuitry prevents recharging unless Rechargeable Battery cell is within specifications and the cell voltage is suitable for charging
Charging Current	115mA

**SPRINT Recharging Base Power Supply (REF 9616)**

Parameter	Specification
Size	Approximately 3.9cm X 3.3cm X 2.4cm
Description	Commercially available USB Power Adapter (with integral plug cap for US market)
Safety Certifications	UL (60950-1); FCC Part 15 class B
Output	5.00V (+/- 0.24V) at up to 1.0A DC (0.15A is required)
Mains Power	90VAC – 264VAC; 50Hz or 60Hz














**SPRINT Hand-Held Remote (REF 9620)**






Parameter	Specification
Size	Approximately 6.5cm X 4cm X 1.7cm
Mass	Approximately 25g
Wireless Communications	BLUETOOTH® (Low Energy)
Internal Battery	Lithium Coin Cell (CR2032) {user replaceable with the use of a screwdriver}

## SYMBOLS & MESSAGES

**Table A: Hand-Held Remote Symbols & Messages**

Table A explains the symbols and messages that appear on the Hand-Held Remote and its screen.

Symbol or Message	Description
	Stimulation ON/OFF button
	Stimulation is ON (Single-Lead or Dual-Leads at the same frequency)
<b>OFF</b>	Stimulation is OFF
<b>+</b>	Increase
<b>-</b>	Decrease
	Home (return to home screen)
	Full Rechargeable Battery
	Mostly full Rechargeable Battery
	Partially full Rechargeable Battery
	Low Rechargeable Battery; Replace and recharge
	Lock switch is off (buttons are enabled)
	Lock switch is on (buttons are disabled)
	Select Light Gray Lead (Systems with Dual-Leads only)
	Select Dark Gray Lead (Systems with Dual-Leads only)
	Light Lead Stimulation is ON (Systems configured to Bimodal only)
	Dark Lead Stimulation is ON (Systems configured to Bimodal only)

Symbol or Message	Description
	Light Lead Stimulation is set to "0" intensity (Dual-Lead Systems only)
	Dark Lead Stimulation is set to "0" intensity (Dual-Lead Systems only)
	Light Lead Stimulation is OFF – timer expired (Systems configured to Bimodal stimulation only)
	Dark Lead Stimulation is OFF – timer expired (Systems configured to Bimodal stimulation only)
	Select Light Lead and Dark Lead to start stimulation simultaneously (Systems configured to Bimodal only)
Session Complete	The treatment session is done
Wireless Error	BLUETOOTH® connection issue has occurred; See Appendix B
Lead Connect Error	A Lead connection issue has occurred; See Appendix B
Internal Error	An issue has occurred; See Appendix B
Recharge Battery	Replace and recharge the Rechargeable Battery
Replace Remote Battery	Replace the Hand-Held Remote Battery
Con	Continue paused session (Systems with Session Treatment only)
New	Start new session (Systems with Session Treatment only)






**Table B: Pulse Generator Lights & Tones**

Table B explains the lights and tones that are output by the Pulse Generator.












Light or Tone	Description
Short beep 5 second Green light	Newly inserted Rechargeable Battery high to medium charge
Short beep 5 second Yellow light	Newly inserted Rechargeable Battery low charge
Short beep flashing Yellow light	Newly inserted Rechargeable Battery critically low charge; Replace and recharge
Short Green light flash	Session started by press of Pulse Generator button or Hand- Held Remote button
Single Blue light flash	Wireless command received
3 short beeps flashing Yellow light	Stimulation stopped due to a low battery <b>OR</b> stimulation stopped due to an error <b>OR</b> internal error
flashing Blue light	Pulse Generator is in BLUETOOTH® pairing mode

**Table C: Label Symbols**

Table C explains the symbols on products and packaging related to the SPRINT® PNS System. Not all symbols apply to the parts provided to you.

Symbol or Message	Description
	Model Number
<b>Rx only</b>	Restricted for sale by or on the order of a physician
	Consult accompanying documents
	Caution: Consult accompanying documents
	Do not reuse
	Do not use if the product sterilization barrier or its packaging is compromised

## APPENDIX D: SYMBOLS & MESSAGES

Symbol or Message	Description
	Sterilized using ethylene oxide
	Non-pyrogenic
	Lot number
<b>SN</b>	Serial Number
 YYYY-MM-DD	Use by date (YYYY-MM-DD): This product should be used before the specified day
	Keep dry
<b>IP 22</b>	The degree of protection from water and dust offered by the Pulse Generator. {unintentional and limited duration exposure to light rain}
 MIN °C MAX °C	Upper and Lower Limits of Temperature for shipping and storage
	Type BF applied part
	Manufacturing date
	Manufacturer
	MR Unsafe
	MR Conditional
	Not made with natural rubber latex



## CONTACTING CUSTOMER SERVICE

You should first attempt to contact your assigned SPR representative. If you're unable to contact your SPR representative, contact your medical provider. If you're unable to reach your SPR representative or provider, please contact SPR Customer Service.

### Via Mail:

SPR Therapeutics, Inc.  
22901 Millcreek Blvd  
Cleveland, OH, 44122 USA

### Via Telephone:

Toll Free: 844-378-9108

### Via Fax:

216-803-0777

### Via Email:

[support@sprtherapeutics.com](mailto:support@sprtherapeutics.com)

MRI SAFETY INFORMATION

The SPRINT System is MR Unsafe – All MRI procedures, no matter the anatomic site, are contraindicated for patients with the SPRINT PNS System. Exposure can cause tissue heating and injury or unwanted stimulation. Pull out the Lead and remove all other System components from the patient before an MRI examination is performed. In the case of a MicroLead fracture beneath the skin resulting in a retained Lead remnant, an MRI examination is safe to perform under the conditions described in the MR Conditional statement below.



A retained Lead Remnant ONLY is MR Conditional – A person with a retained Lead remnant may be safely scanned anywhere in the body at 1.5T or 3.0T under the following conditions. Failure to follow these conditions may result in injury.

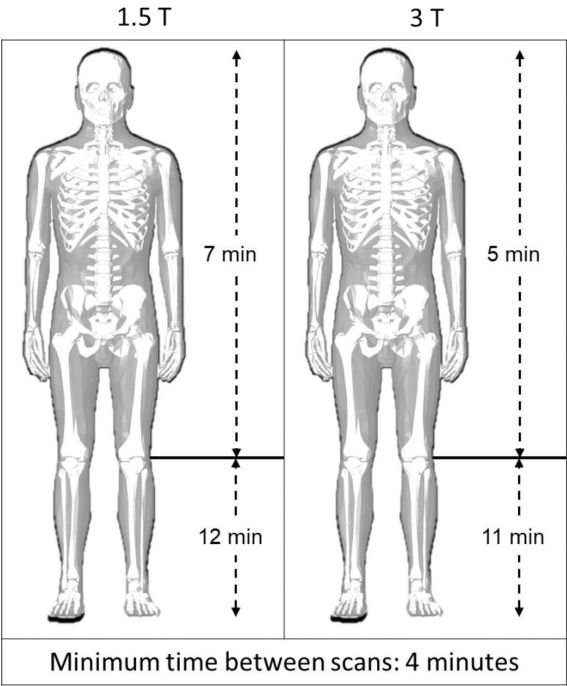


Parameter	Condition
Device Name	Retained MicroLead remnant
Static Magnetic Field Strength (B0)	1.5T and 3T
MR Scanner Type	Cylindrical
B0 Field Orientation	Horizontal
Maximum Spatial Field Gradient	20 T/m (2,000 G/cm)
Maximum Gradient Slew Rate	200 T/m/s per axis
RF Excitation	Circularly Polarized (CP)
RF Transmit Coil Type	Integrated Whole Body Transmit Coil
Operating Mode	Normal Operating Mode
RF Conditions	Maximum Whole-body SAR: 2 W/kg
	Maximum Head SAR: 3.2 W/kg
	Maximum Partial Body SAR: 2-10 W/kg*

Parameter	Condition
Scan Duration	For 1.5 T MR Scanner: Scan for up to 7 minutes for landmarks above the knee and 12 minutes for landmarks below the knee. Wait a minimum of 4 minutes before the next imaging session.
	For 3 T MR Scanner: Scan for up to 5 minutes for landmarks above the knee and 11 minutes for landmarks below the knee. Wait a minimum of 4 minutes before the next imaging session.
Scan Regions	Any landmark is acceptable
Image Artifact	The presence of the MicroLead remnants may produce an image artifact of 0.8 cm. Some manipulation of scan parameters may be needed to compensate for the artifact.

\* The limit ( pbSAR<sub>lim</sub> ) scales dynamically with the ratio of exposed patient mass to patient mass:  
$$\text{pbSAR}_{\text{lim}} = 10\text{W/kg} - (8\text{W/kg} \times \frac{\text{exposed patient mass}}{\text{patient mass}} )$$

Acceptable Scanning Regions & Duration





**NOTE:** There should be no section of Lead visible above the skin.



**NOTE:** If a Lead is placed in an individual with an existing retained Lead remnant, the new Lead should not be placed in a location where it could touch the original Lead remnant. During MRI, two MicroLead fragments touching can result in an increase in temperature of the Lead remnants and surrounding tissue where they touch.

### MRI Safety Card

If your physician believes that you may have a retained Lead remnant, carry the MRI safety card with you (included with your kit).

## TSA Notification: Individual with Medical Device

I have an external medical device (neurostimulator) attached to my body for pain management that may affect my screening.

For product information visit:  
**SprintPNS.com**

I understand that alternate procedures providing an equivalent level of security screening are available and can be done in private. I also understand that presenting this notification does not exempt me from screening.

### Patient

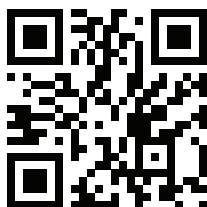
For questions regarding screening please visit: TSA Cares at **TSA.gov**

You may request a Passenger Support Specialist (PSS) or Supervisory TSA Officer at the checkpoint if you require further assistance.





## Patient Instructional Videos



Scan this QR code with a smart phone camera or visit:  
[sprtherapeutics.com/patients/patient-resources/](https://sprtherapeutics.com/patients/patient-resources/)



22901 Millcreek Blvd  
Cleveland, OH, 44122 USA  
Call 844-378-9108 | Fax 216-803-0777

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support@sprtherapeutics.com